

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2014-1364

CLASSEN IMMUNOTHERAPIES, INC.,
Plaintiff-Appellant

v.

SHIONOGI, INC.
Defendant-Appellee

Appeal from the United States District Court for the District of Maryland in case No. 13-cv-0921, Judge Roger W. Titus

MOTION TO STAY PROCEEDINGS PENDING THE FILING AND
DISPOSITION OF A PETITION FOR WRIT OF CERTIORARI

MOTION TO DELAY SCHEDULE FOR 2 WEEKS
PENDING DECISION ON MOTION TO STAY

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Pursuant to Rules 26 and 27 of the Federal Rules of Appellate Procedure, Appellant Classen Immunotherapies, Inc. respectfully moves this Court to stay all proceedings in this appeal pending the filing and disposition of a timely petition for a writ of certiorari with the Supreme Court of the United States in the related appeal styled *Classen Immunotherapies v. Somaxon Pharmaceuticals* 2013-1405.¹ A stay is warranted because Classen's petition for certiorari in the Somaxon case concerns the exact issues of law that are at issue in this appeal. Namely, whether the application of the Safe Harbor provision of §271(e)(1) extends to commercial activity which relies upon information previously submitted to the FDA but carries no additional reporting requirement and whether steps performed as acts of infringement under 35 U.S.C §154 can be combined with steps performed as acts of infringement under 35 U.S.C §271. A stay will allow the Supreme Court to rule on and give guidance on the Federal Circuit's ruling in the Somaxon case, which ruling will be directly applicable to – and likely dispositive of – the appeal here.

Classen also asks the Court pursuant to Fed. R. App. P. 26(b) to extend the briefing schedule for two weeks while the Motion to Stay is being considered by this Court.

I. INTRODUCTION

Classen sued Shionogi alleging that certain activities surrounding Shionogi's commercialization of drugs containing glycopyrrolate infringe the claims of U.S. Patent Numbers 7,653,639 ("the '639 patent") and 7,984,069 ("the '069 patent"). The Complaint was dismissed by the District of Maryland, based on the safe harbor provisions of 35 U.S.C. §271.

Prior to the Shionogi action, Classen sued Somaxon Pharmaceuticals, alleging that certain activities surrounding Somaxon's commercialization of the drug Silenor. The First

¹ Shionogi's counsel indicated that they do not plan to file a reply to this motion and take no position on the request for a stay.

Amended Complaint in that case was dismissed by the District Court for the Central District of California on April 11, 2013. An appeal was filed on May 3, 2013 (Appeal 2013-1405). On January 17, 2014, this Court issued a non-precedential opinion affirming without comment the lower court decision.

Classen intends to file a petition for certiorari with the United States Supreme Court seeking review of this Court's affirmation of the trial court decision in *Classen v. Somaxon*. A draft of the petition for certiorari has been prepared and counsel has been retained for presenting the appeal to the Supreme Court. The petition is set to be filed in June 2014.

II. STAY PENDING A DECISION ON THE SOMAXON PETITION FOR CERTIORARI BENEFITS THE COURT AND THE PARTIES

“The power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.” *Landis v. North American Co.*, 299 US 248, 254 (1936). In this instance, a stay pending the Supreme Court’s decision on Classen’s petition for certiorari would save time and resources for the Court and for all parties involved.

If the Supreme Court were to grant certiorari in the Somaxon case, the very same aspects of law that are at issue in this appeal would be heard by the Supreme Court. A decision in Classen’s favor would greatly simplify the briefing and hearing burden before this court. A decision by the Supreme Court either to deny certiorari or a decision on the merits that goes against Classen would likewise simplify or eliminate this appeal altogether.

A stay would not cause hardship to Shionogi because there has been no judgment against them in the trial court or at the appeal level. Thus, Shionogi’s business is not affected by an injunction or damages award while Classen’s appeals run their course. In fact, a stay would benefit Shionogi in that it would not be obligated to address an appeal in this case until the

Supreme Court rules on the disputed issues of law. Classen respectfully submits that the balance of equities favors granting a stay pending a decision on Classen's petition for certiorari in the Somaxon case.

Accordingly, Classen respectfully requests that this Court stay the current proceedings pending Classen's imminent Petition for Certiorari to the Supreme Court in *Classen v. Somaxon*.

III. A SHORT EXTENSION PENDING DECISION ON THIS MOTION TO STAY IS WITHIN THE COURT'S POWER

Rule 26(b) empowers this Court to "extend the time prescribed by these rules or by its order to perform any act." Furthermore, the Court may immediately institute the extension of time without waiting for a response from the non-movant. Fed. R. App. P. 27(b) ("The court may act on a motion for a procedural order—including a motion under Rule 26(b)—at any time without awaiting a response.")

Classen's opening brief is set to be filed on Monday, May 19, 2014 under the current case schedule. Classen respectfully requests that this court grant a two week extension for filing the opening brief, during which time the court can rule on the preceding motion to stay pending certiorari.

IV. CONCLUSION

Appellant Classen Immunotherapies respectfully requests that this court impose an immediate stay on this appeal, pending the Supreme Court's decision on Classen's upcoming petition for certiorari in Appeal No. 2013-1405, styled *Classen Immunotherapies, Inc. v. Somaxon Pharmaceuticals, Inc.* The Supreme Court appeal in that case presents issues of law that are identical to those that will be presented in this appeal. Accordingly, a stay pending the Supreme Court's decision on Classen's petition for certiorari will preserve judicial resources and

will relieve the burden on appellee Shionogi, which would otherwise be obligated to prepare briefs in this Court.

Appellant also requests that this court grant a two week extension of time for Appellant to file its opening appeal brief in this case, while the Court decides on the preceding Motion to Stay.

May 16, 2014

Respectfully Submitted

By /s/ Joseph J. Zito

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